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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,273	03/17/2004	Gustavo C. Rodriguez	31162B	4202

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EXAMINER	
ROYDS, LESLIE A	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 10/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/802,273	RODRIGUEZ, GUSTAVO C.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26* is/are rejected.

7)☒ Claim(s) *25 and 26* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *02 August 2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-26 are presented for examination.

A request for continued examination under 37 C.F.R. 1.114, including the fee set forth in 37 C.F.R. 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R. 1.114, and the fee set forth in 37 C.F.R. 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 C.F.R. 1.114. Applicant's submission and Information Disclosure Statement (IDS) filed August 2, 2006 has been received and entered into the present application. As reflected by the attached, completed copy of form PTO/SB/08A (nine pages total), the Examiner has considered the cited references.

Claims 1-26 are pending and are under examination. Claims 1-17 are amended and claims 20-26 are newly added.

Applicant's arguments, filed August 2, 2006, have been fully considered but they are not deemed to be persuasive. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and objections are either reiterated or newly applied. They constitute the complete set of rejections and objections presently being applied to the instant application.

Objection to the Claims (New Grounds of Objection)

Claims 25-26 are objected to under 37 C.F.R. 1.75 as being substantial duplicates of present claims 18 and 19, respectively. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight different in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. Please reference MPEP §706.03(k). Applicant may wish to consider canceling or amending claims 25 and 26, since they are drawn to the same subject matter already claimed in present claims 18 and 19.

Claim Rejections - 35 USC § 112, Written Description Requirement

(New Grounds of Rejection)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 20-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Present claims 20-22 are directed to the hormonal regimen of claim 15 (i.e., wherein said regimen is multi-phasic, with one phase having a daily dosage of norgestimate of at least 0.5 mg) wherein another phase has a daily dosage of norgestimate of 0.18-0.25 mg (claim 20); 0.18 mg (claim 21); or 0.215 mg (claim 22).

In particular, Applicant has failed to provide adequate written support to now claim an additional phase of the hormonal regimen wherein the dosage of norgestimate is 0.18-0.25 mg (claim 20); 0.18 mg (claim 21); or 0.215 mg (claim 22).

Regarding Applicant's newly added claims 20-22, Applicant states, "Applicant has added new claims 20-26. The support for claims 20-22 comes in part from Table 2 with respect to the regimens in the art known for tri-phasic norgestimate. The application clearly contemplates taking known OCP compositions and changing them to obtain the benefits of the invention. The invention also describes taking such known hormonal regimens and increasing one of the phases to a higher level. In the application at pages 29-30, Applicant states that the invention includes expanding the clinical usages of progestin drugs beyond the current use of these drugs as oral contraceptives. Applicant specifically states that these can be accomplished by altering the dosage of the progestin product...Applicant specifically

describes ways of altering OCP formulations, including multi-phasic OCP regiments where at least one of the daily dosages has at least 0.5 mg norgestimate. (Application page 35, 19-26)...Here, a person skilled in the art would certainly understand that Applicant's invention included starting with known OCP formulations and altering them in terms of progestin dosage as taught by the application. One product that is described in Table 2 is the tri-phasic norgestimate with dosages 0.18, 0.215 and 0.25 mg norgestimate. The application specifically states that one can have a multi-phasic norgestimate regimen where one of the phases now has 0.5 mg norgestimate. Thus, a person skilled in the art would immediately envisage that this was part of the invention disclosed in the application." (Applicant's remarks, paragraph bridging pages 7-8)

The disclosure of prior art multi- or tri-phasic regimens containing norgestimate in amounts of, for example, 0.18 mg, 0.215 mg or 0.25 mg, does not provide adequate written support to now claim a multi-phasic hormonal regimen wherein one of the phases contains at least 0.5 mg norgestimate and any one other phase is a known prior art hormonal phase with 0.18, 0.215 or 0.25 mg norgestimate. The application fails to disclose the actual combination of the regimen phase that Applicant regards as the novel concept of the invention (i.e., at least 0.5 mg norgestimate in combination with 20-35 mcg ethinyl estradiol equivalent) with a hormonal regimen of the prior art (i.e., tri-phasic regimens of norgestimate with 0.18, 0.215 or 0.25 mg norgestimate). It is not sufficient that Applicant merely disclose that the dosage amounts of the progestin product may be altered and then relies upon such a disclosure to support the combination of a hormonal regimen with one phase of at least 0.5 mg norgestimate in combination with another phase already used in the prior art. In the absence of either an explicit or implicit suggestion of combining such phases into a single hormonal regimen for administration, the disclosure fails to provide adequate written support for the regimen(s) now claimed in present claims 20-22.

Applicant relies upon MPEP §2163.02 in support of their assertion that the present disclosure provides adequate written support for newly added claims 20-22. However, as stated in this section of the

MPEP, "An objective standard for determining compliance with the written description requirement is, 'does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed.'" In the present case, Applicant has failed to point out the specific disclosure that provides sufficient written support to now claim the actual combination of a phase with at least 0.5 mg norgestimate in conjunction with a known prior art norgestimate phase of 0.18, 0.215 or 0.25 mg norgestimate.

Considering the teachings provided in the specification as originally filed, Applicant has failed to provide the necessary teachings, by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams and formula that fully set forth the claimed invention, in such a way as to reasonably convey to one skilled in the relevant art that Applicant had possession of the concept of a multi-phasic hormonal regimen wherein one norgestimate phase is at least 0.5 mg and another phase has a daily dosage of 0.18-0.25 mg, specifically, 0.18 mg or 0.215 mg.

Accordingly, for these reasons, claims 20-22 are properly rejected under 35 U.S.C. 112, first paragraph, for failing to comply with the written description requirement.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 10, 12-15, 17-18 and 24-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Pasquale (U.S. Patent No. 4,544,554; 1985).

Pasquale teaches tri-phasic oral contraceptive regimens comprising a estrogen and a progestogen component (see abstract), provided in a pharmaceutical unit, such as a transparent package having 28

dosage units arranged sequentially and consisting of 7 tablets for the first phase, 7 tablets for the second phase, 7 tablets for the third phase and followed by 7 placebo units, wherein a single tablet is to be taken each day over a period of 28 days (col.3, lines 38-45). Pasquale teaches the estrogen component in a daily dosage amount equivalent to 0.02-0.05 mg (i.e., 20-50 mcg) 17alpha-ethinyl estradiol (col.2, lines 47-54), wherein the preferred estrogen is 17alpha-ethinyl estradiol (col.2, lines 59-60). Pasquale teaches norgestimate (i.e., D-17beta-acetoxy-13beta-ethyl-17alpha-ethinyl-gon-4-en-3-one oxime) as a preferred progestogen component (col.3, lines 10-12).

Please reference the exemplary regimens discussed as Examples 2 and 4 of Pasquale at columns 4-5. Example 2 teaches a tri-phasic regimen comprising a first phase of 0.035 mg 17alpha-ethinylestradiol with 0.50 mg norgestimate; a second phase of 0.035 mg 17alpha-ethinylestradiol with 0.75 mg norgestimate; and a third phase of 0.035 17alpha-ethinylestradiol with 1.0 mg norgestimate. Thus, total norgestimate administered over the entire regimen is equivalent to (0.5 mg/tablet x 7 tablets)+(0.75 mg/tablet x 7 tablets)+(1.0 mg/tablet x 7 tablets) = 0.25+5.25+7=12.5 mg norgestimate (i.e., at least 8 mg norgestimate as required by claims 17 or 24 or at least 12 mg norgestimate as required by claims 18 or 25). Example 4 teaches a tri-phasic regimen comprising a first phase of 0.035 mg 17alpha-ethinylestradiol with 0.18 mg norgestimate; a second phase of 0.035 mg 17alpha-ethinylestradiol with 0.215 mg norgestimate; and a third phase of 0.035 mg 17alpha-ethinylestradiol with 0.25 mg norgestimate.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pasquale (U.S. Patent No. 4,544,554; 1985) in view of Elliesen et al. (WO 97/11680; 1997).

Pasquale teaches tri-phasic oral contraceptive regimens comprising a estrogen and a progestogen component (see abstract), provided in a pharmaceutical unit, such as a transparent package having 28 dosage units arranged sequentially and consisting of 7 tablets for the first phase, 7 tablets for the second phase, 7 tablets for the third phase and followed by 7 placebo units, wherein a single tablet is to be taken each day over a period of 28 days (col.3, lines 38-45). Pasquale teaches the estrogen component in a daily dosage amount equivalent to 0.02-0.05 mg (i.e., 20-50 mcg) 17alpha-ethinyl estradiol (col.2, lines 47-54), wherein the preferred estrogen is 17alpha-ethinyl estradiol (col.2, lines 59-60). Pasquale teaches norgestimate (i.e., D-17beta-acetoxy-13beta-ethyl-17alpha-ethinyl-gon-4-en-3-one oxime) as a preferred progestogen component (col.3, lines 10-12).

Please reference the exemplary regimens discussed as Examples 2 and 4 of Pasquale at columns 4-5. Example 2 teaches a tri-phasic regimen comprising a first phase of 0.035 mg 17alpha-ethinylestradiol with 0.50 mg norgestimate; a second phase of 0.035 mg 17alpha-ethinylestradiol with 0.75 mg norgestimate; and a third phase of 0.035 17alpha-ethinylestradiol with 1.0 mg norgestimate. Thus, total norgestimate administered over the entire regimen is equivalent to (0.5 mg/tablet x 7 tablets)+(0.75 mg/tablet x 7 tablets)+(1.0 mg/tablet x 7 tablets) = 0.25+5.25+7=12.5 mg norgestimate (i.e., at least 8 mg norgestimate as required by claims 17 or 24 or at least 12 mg norgestimate as required by claims 18 or 25). Example 4 teaches a tri-phasic regimen comprising a first phase of 0.035 mg 17alpha-ethinylestradiol with 0.18 mg norgestimate; a second phase of 0.035 mg 17alpha-ethinylestradiol with 0.215 mg norgestimate; and a third phase of 0.035 mg 17alpha-ethinylestradiol with 0.25 mg norgestimate.

The differences between the Pasquale reference and the presently claimed subject matter lies in that the reference fails to teach norgestimate in dosages of 0.8 mg (claim 11), greater than 1.0 mg (claims

7-9), or total norgestimate of at least 20 mg (claims 29 or 26); or a multi-phasic regimen with another phase having norgestimate in an amount of 0.2-0.3 mg (claims 16 or 23), 0.18-0.25 mg (claim 20), 0.18 mg (claim 21), or 0.215 mg (claim 22).

However, the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains because:

Elliesen et al. provides teachings that frequent modifications to the progesterone dosage level is necessary to deal with hormonal fluctuations during menopause and also due to physiological differences between women. Elliesen et al. states, "Modifying the progesterone dosage level also is frequently necessary during menopause to deal with menses irregularities. Thus, a fixed combination of an estrogen dosage and a progestogen dosage that is suitable for all menopausal women is impossible to design, for a variety of reasons. One reason is the wide variation from individual to individual in the resorption rate which exists with all modes of administration except intravenous, which is not practiced in HRT. These differences in bioavailability can reach 100% or more. For example, the bioavailability of estradiol orally averages 5% of the oral dose, which means that in an individual it can be as low as 3% or as high as 6%. Another reason why a fixed combination is not suitable is because of variations in body weight and fat mass proportion, which has an endocrine function because it contains enzymes to transform hormonal precursors into estrogens. A third reason is the interaction between estrogens and progestogens, i.e., progestogens may only become effective in the presence of estrogens because they stimulate the production of progestogen receptors." (page 2, third and fourth paragraphs)

In light of such a teaching, it would have been *prima facie* obvious to one of ordinary skill in the art to modify the specific dosage amounts of norgestimate as taught by Pasquale to tailor the regimen to fit the hormonal requirements of the subject to whom it was administered. In particular, one of skill in the art would have been motivated to augment or increase the dosage of norgestimate to, for example, 0.8 mg

(claim 11), greater than 1.0 mg (i.e., 1.2 or 1.8 or 2.5 mg; claims 7-9), or total norgestimate of at least 20 mg (claims 29 or 26), depending on the hormonal needs of the female (i.e., time of reproductive cycle, menses, menopause, etc.) and physiological factors (i.e., age, weight, lean muscle/fat mass ratio, etc.). In particular, increasing the progestogen dosage would have naturally commended itself to the skilled artisan in order to maintain an efficacious anti-fertility level of the progestogen hormone when accounting for differing, and possibly slower, rates of hormone resorption and metabolism among individual female subjects.

Applicant is further reminded that should he rely upon the fact that a particular amounts of the progestogen agent is critical to the invention, Applicant must make an objective showing that the claimed range achieves unexpected results relative to the prior art range [*In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990)] and that the unexpected results demonstrate a marked improvement over that achieved using the amounts of the prior art such that the difference shown in actually a difference in kind and not just a difference in degree [*In re Waymouth*, 499 F.2d 1273, 1276, 182 USPQ 290, 293 (CCPA 1974)]. Furthermore, Applicant is further advised that should he rely upon unexpected results to patentably distinguish over the prior art, the present claims must be limited to that embodiment which is, in fact, unexpected.

Regarding the use of an additional phase having norgestimate in an amount of 0.2-0.3 mg (claims 16 or 23), 0.18-0.25 mg (claim 20), 0.18 mg (claim 21), or 0.215 mg (claim 22), Pasquale expressly teaches an exemplary regimen wherein norgestimate is administered concomitantly with 0.035 mg 17alpha-ethinylestradiol in three phases of 0.18 mg norgestimate, 0.215 mg norgestimate and 0.25 mg norgestimate. Pasquale teaches the same contraceptive efficacy of this regimen as compared to the regimen of Example 2 (i.e., norgestimate in an amount of at least 0.5 mg). The skilled artisan would have been motivated to employ such an alternate phase in the hormonal regimen(s) disclosed by Pasquale because prolonged treatment with excessively high levels of progestogen can lead to hormonal side

effects, such as, but not limited to, those taught by Elliesen et al. at the top of page 2, including breast tenderness, nausea, edema, menstrual disorders, etc., and, therefore, the use of a multi-phasic regimen wherein the dosage amounts of the progestogen are varied such that the efficacy of the regimen is maintained while avoiding the adverse side effects typically seen with protracted administration of high levels of progestogen(s) would have been *prima facie* obvious to one of ordinary skill in the art.

Double Patenting

Obviousness-Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-26 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over patented claims 1 and 14 of U.S. Patent No. 6,977,250, previously set forth as a provisional obviousness-type double patenting rejection over U.S. Patent Application No. 09/954,082, from which the '250 patent issued, in view of newly relied upon Elliesen et al. (WO 97/11680; 1997). The rejection is based upon the same grounds as set forth in the non-final rejection dated April 1, 2005, in light of the following additional comments:

An obviousness-type double patenting rejection is appropriate where the conflicting claims are

not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s).

Although the conflicting claims are not identical, the present claims render the patented claims obvious.

The present claims clearly provide for a hormonal regimen, considered to inherently be a pharmaceutical composition because it comprises the combination of both two hormonal products, which must necessarily be pharmaceutically acceptable components for administration to a subject, comprising both an estrogen product (e.g., ethinyl estradiol) and a progestin product (i.e., norgestimate), which are the required components of the patented composition. Though the claims differ in that the present claims do not expressly recite a ratio of progestin to estrogen or 239:1 by weight in norethindrone/ethinylestradiol equivalents, Elliesen et al. teaches that, "Thus, a fixed combination of an estrogen dosage and a progestogen dosage that it suitable for all menopausal women is impossible to design, for a variety of reasons. One reason is the wide variation from individual to individual in the resorption rate which exists with all modes of administration except intravenous, which is not practiced in HRT. These differences in bioavailability can reach 100% or more. For example, the bioavailability of estradiol orally averages 5% of the oral dose, which means that in an individual it can be as low as 3% or as high as 6%. Another reason why a fixed combination is not suitable is because of variations in body weight and fat mass proportion, which has an endocrine function because it contains enzymes to transform hormonal precursors into estrogens. A third reason is the interaction between estrogens and progestogens, i.e., progestogens may only become effective in the presence of estrogens because they stimulate the production of progestogen receptors." (page 2, third and fourth paragraphs) Therefore, variations in the optimum dosage amounts of estrogen and/or progestin would have been reasonably expected by, and well within the skill of, the skilled artisan motivated by the desire to determine the most

appropriate dosage amounts and, thus, ratio amounts, of estrogen and progestin based upon the hormonal needs and physiologic differences among women. In other words, the dosage amounts of both the estrogen and progestin would have been reasonably expected to vary and, therefore, the optimum dosage amounts determined by the skilled artisan in the present claims are not seen to patentably differ from those that would have been routinely determined by the skilled artisan in the patented claims.

Accordingly, in the absence of additional remarks to the contrary or any Terminal Disclaimers, the rejection of the present claims over the now patented claims 1 and 14 of U.S. Patent No. 6,977,250 (previously U.S. Patent Application No. 09/954,082) remains proper and is **maintained**.

Conclusion

Rejection of claims 1-26 remains proper and is **maintained**.

No claims of the present application are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leslie A. Royds
Patent Examiner
Art Unit 1614

October 12, 2006

Ardin H. Marschel 10/14/06
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER